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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/724,586

Applicant(s)

SAKOWICZ ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-9,11-13,50-52,54-56 and 59-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 8,9,11,13,50-52,54,59,64,68,74-76,81-82 is/are allowed.
- 6) ☒ Claim(s) 2, 12, 55-56, 60-63, 65-67, 69-73 and 83-88 is/are rejected.
- 7) ☒ Claim(s) 2,4,5,7,12,63 and 77-80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Claim 7 reites sequences without an identifying sequence number_____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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DETAILED ACTION

Amendment Entry

1. Applicants amendment filed March 17, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claims 3, 6, 10, 49 and 53 have been cancelled. Claims 1-2, 7-9, 11-12, 50-52 and 54-56 have been amended. Claims 59-88 have been newly added. Claims 1-2, 4-5, 7-9, 11-13, 50-52, 54-56 and 59-88 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 6,8-10 and 53-56 under 35 U.S.C. 112, second paragraph;

b)The written description rejection of claims 1-13 and 49-56 under 35 U.S.C. 112, first paragraph; and

c) The enablement rejection of claims 1-13 and 49-56 under 35 U.S.C. 112, first paragraph.

Response to Arguments

3. Applicant's arguments with respect to claims 1-13 and 49-56 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Objections

4. Claims 2, 4-5, 12, 63, and 77-80 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claims 2, 4-5, 12, 63 and 77 are drawn to a nucleic acid that encodes the entire SEQ ID NO:1 while claim 1 only encodes the amino acids 1 to 357 of SEQ ID NO:1; thus the dependant claims fail to further limit claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 55-56, 61-62, 65-67, 69-73 and 87-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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Claims 55 and 56^{are} drawn to the nucleotide sequences comprising nucleic acids either 1327 to 1803 or 1804 to 2352 of SEQ ID NO:2 that encode a protein having plus end directed microtubule motor activity. There is no evidence of record of a relationship between the structure of the instantly claimed polynucleotides and the plus end directed motor activity. The specification fails to provide any reliable information about the structure and the corresponding function. Rather the specification teaches that plus directed microtubule motor activity would only be found within nucleotides 1-1071, and that nucleotides 1329-1803 refer to the stalk domain which fails to have motor activity; nucleotides 1804 to 2352 refers to the tail domain which fails to have motor activity. See pages 22-23 of the instant specification. There is no evidence that the claimed isolated nucleic acid sequences have a known structural and functional relationship to the plus directed motor activity. Moreover, in absence of a start and stop codon and in absence of the specification to provide clear protocol by which the hyphal fungus polypeptide/ polynucleotide comprising SEQ ID NO: 2 was isolated from the microorganism of interest; it is not readily apparent to a person of skill in the art that the claimed polynucleotide is expressed by the hyphal fungus.

Claims 61, 65, 66 and 69-73 are drawn to isolated nucleic acid sequences encoding proteins comprising amino acids 358 to 442, 443 to 601 or 602 to 784 of SEQ ID NO:1. The specification does not provide functional or structural characterization of the full-length open reading frame of the instantly claimed polynucleotides comprising amino acids 358 to 442, 443 to 601 or 602 to 784 of SEQ ID NO:1. The specification does not provide a clear protocol by which the claimed polynucleotide was isolated from

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the hyphal fungus at the time the invention was made. The specification does not provide structural characterization of the complete open reading frame of the hyphal fungus, i.e., including a start and stop codon. In the instant case, the classic start and stop codons are missing from the beginning and end of the nucleic acid from which the sequences of the polypeptide were derived. The specification alleges functionality, i.e., having plus end directed microtubule motor activity, however similar polynucleotides and corresponding polypeptides in the art are highly variant and all begin and end with a classic start and stop codon. In view of the lack of evidence in the specification as filed, it is apparent that one skilled in the art would recognize that applicants were not in possession, at the time of filing the instant application, of a genus of the polynucleotides. Absent characterization of the start and stop codons, the genus of the hyphal fungus polynucleotides that encode polypeptides comprised in SEQ ID NO:1 is highly diverse and variant.

Claims 62, 67 and 87-88 are drawn to the polynucleotide comprising amino acids 358 to 442, 443 to 601 or 602 to 784 of SEQ ID NO:1 and having plus end directed microtubule motor activity, there is no evidence of record of a relationship between the structure of the instantly claimed polynucleotides and the plus end directed motor activity. The specification fails to provide any reliable information about the structure and the corresponding function. There is no evidence that the claimed isolated nucleic acid sequences have a known structural and functional relationship to other full-length proteins. The art indicates that the structure of the polypeptides and polynucleotides would be expected to be highly variant. Moreover, in absence of a start and stop codon

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and in absence of the specification to provide clear protocol by which the hyphal fungus polypeptide/ polynucleotide comprising SEQ ID NO: 1 was isolated from the microorganism of interest; it is not readily apparent to a person of skill in the art that the claimed polynucleotide is expressed by the hyphal fungus.

In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification sufficient to show that Applicants were in possession of the polynucleotides as asserted in the claims.

6. Claims 55, 56, 62, 67 and 87-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2 having plus end directed microtubule motor activity; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1 having plus end-directed microtubule motor activity; and isolated nucleic acid sequences encoding a microtubule motor protein wherein the protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443 to 601 or 601 to 784 of SEQ ID NO:1 and has plus end directed microtubule motor activity.

Applicant did not point to support in the specification for such nucleic acid sequences that have plus directed motor activity when such activity is only found within nucleotides 1 to 1071 or amino acids 1 to 357. See the specification at page 22. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of nucleic acid sequences that encode proteins that comprise the motor activity. Thus, there appears to be no teaching of isolated nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2 having plus end directed microtubule motor activity; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1 having plus end-directed microtubule motor activity; and isolated nucleic acid sequences encoding a microtubule motor protein wherein the protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443to 601 or 601-to 784 of SEQ ID NO:1 and has plus end directed microtubule motor activity. Applicant has pointed to various pages of the instant specification and claims for support of the amendment, however it appears that the entire specification appears to fail to recite support for the newly recited sequences with the ability to have the plus end directed microtubule motor activity. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of such nucleic acids as recited by the newly added amendments. Therefore, the new claims incorporate new matter and are accordingly rejected.

7. Claims 55, 56, 62, 67 and 87-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated nucleic acid sequence comprising nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2 and encoding a protein having plus end directed microtubule motor activity; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1 having plus end-directed microtubule motor activity; and an isolated nucleic acid sequences encoding a microtubule motor protein wherein the protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443 to 601 or 601 to 784 of SEQ ID NO:1 and has plus end directed microtubule motor activity.

The specification at pages 22-23 teaches that plus end directed motor activity is found when the sequence comprises the motor domain and such activity is only found within nucleotides 1 to 1071 or amino acids 1 to 357. There is no teaching that following nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1; and isolated nucleic acid sequences encoding a microtubule motor protein wherein the protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443 to 601 or 601 to 784 of SEQ ID NO:1 has plus end directed microtubule motor activity, since the recited claims fail to comprise the motor domain necessary to encode motor activity. The specification is not enabled for any of the claimed polynucleotides, because the specification fails to teach sequences can retain the claimed characteristic of having plus end directed microtubule motor activity without

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having the motor region. The specification lacks any written description of a structure or relevant identifying characteristics of a representative number of polynucleotides encoding a representative number of proteins sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. The specification teaches what the critical nucleic acids are which are necessary to have motor activity, yet the claimed sequences fail to comprise said regions. The specification fails to teach the identity of any nucleic acid sequences with the claimed abilities. Therefore, the specification fails to enable an isolated nucleic acid sequence comprising nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2 and encoding a protein having plus end directed microtubule motor activity; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1 having plus end-directed microtubule motor activity; and isolated nucleic acid sequences encoding a microtubule motor protein wherein the protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443 to 601 or 601 to 784 of SEQ ID NO:1 and has plus end directed microtubule motor activity.

Moreover, applicant failed to specifically point to the identity or provide structural characteristics of nucleic acid sequences that encode proteins that comprise the motor activity. Thus, there appears to be no teaching of isolated nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2 having plus end directed microtubule motor activity; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1 having plus end-directed microtubule motor activity; and an isolated nucleic acid sequences encoding a microtubule motor protein wherein the

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protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443 to 601 or 601 to 784 of SEQ ID NO:1 and has plus end directed microtubule motor activity. Applicant has pointed to various pages of the instant specification and claims for support of the amendment, however it appears that the entire specification fails to recite support for the newly recited sequences with the ability to have the plus end directed microtubule motor activity. The specification only teaches that such sequences can be encoded.

In absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate nucleic acids would be. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of a isolated nucleic acid sequence comprising nucleotides 1327-1803 or 1804-2352 of SEQ ID NO:2 and encoding a protein having plus end directed microtubule motor activity; an isolated nucleic acid sequence encoding a protein comprising amino acids 443-601 or 602 to 784 of SEQ ID NO:1 having plus end-directed microtubule motor activity; and an isolated nucleic acid sequences encoding a microtubule motor protein wherein the protein has a domain that has greater than 95% amino acid sequence identity to amino acids 443 to 601 or 601 to 784 of SEQ ID NO:1 and has plus end directed microtubule motor activity.

The claimed nucleic acids would not predictably result in the microtubule motor protein comprising plus end directed microtubule motor activity. No working examples are shown containing the missing information. Without such information, one of skill in

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the art could not predict the function of the desired polynucleotide. Accordingly, one of skill in the art would be required to perform undue experimentation to use the claimed nucleic acid to produce such isolated nucleic acid sequences. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

8. Claims 2, 12, 60, 63, 70 and 83-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 2, 12 and 63 are unclear. The claims are drawn to an isolated nucleic acid sequence wherein the protein specifically binds to polyclonal antibodies to *Thermomyces lanuginosus* gamma protein listed as SEQ ID NO:1. It is unclear to what the claim is referring, since the claims are actually drawn to the nucleic acid and not to the function of the protein and its ability to bind polyclonal antibodies. It is unclear what applicants are attempting to claim, i.e., the activity of the polyclonal antibodies bind both SEQ ID NO:1 and the protein encoded by the nucleic acid sequence. It is unclear that the epitopes which the polyclonal antibody binds to is found on the isolated nucleic acid sequence that encodes amino acids 1 to 357 of SEQ ID NO:1 and to the *Thermomyces lanuginosus* gamma protein listed within the entire 784 amino acids of SEQ ID NO:1.

The term "specifically binds" in the claims is a relative term that renders the claim indefinite. The term "specifically binds" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The

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metes and bounds of the claim cannot be ascertained, thus clarification is required to overcome the rejection.

10. Dependant claim 60 is drawn to the protein having plus end directed microtubule motor activity however the claim is also drawn to the nucleic acid sequence yet further dependent on claim 11 which is drawn to an expression vector. Therefore claim 60 is confusing with its recitation of protein activity when the claim is drawn to the protein and the expression vector. Clarification is required to overcome the rejection.

11. Claim 70 is unclear. The claim is drawn to the isolated nucleic acid of claim 1 wherein the encoded protein further comprises at least one of amino acids 602 to 784 of SEQ ID NO:1, 358 to 442 of SEQ ID NO:1 and amino acids 443 to 601 of SEQ ID NO:1. It is unclear if the claim is drawn to encoding at least one additional amino acid found within the recited regions or encoding something else. The metes and bounds of the claim is unclear, therefore clarification is required to overcome the rejection.

12. Claims 85-88 are indefinite because ^{they} recites using the comparison algorithm. Applicants have claimed the algorithm that is impermissible and requires deletion because the claim is devoid of any limitation on the manipulation of the phylogenetic parameters. This attempt to incorporate subject matter into the patent by reference is improper because PTO policy does not permit the PTO to exercise any control over

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algorithm, its alignment methods or the accuracy of the information contained therein.

Appropriate correction is required.

Sequence Compliance

13. Claim 7 fails to comply with sequence requirements. Claim 7 recites sequences without giving all the sequences identification numbers. This claim contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). The claim must comply with sequence requirements.

Allowable Subject Matter

14. Claims 1,8,9,11,13, 50-52,54,59,64-68,74-76 and 81-82 are allowed.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
June 4, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600